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PATENT

Customer No. 22,582

Attorney Docket No. 05394.0011

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of)
Stewart COLE et al.)
Serial No. 09/673,476) Group Art Unit: 1634
Filed: November 30, 2000) Examiner: A. Chakrabarti

For: A METHOD FOR ISOLATING A POLYNUCLEOTIDE OF INTEREST FROM THE
GENOME OF A MYCOBACTERIUM USING A BAC-BASED DNA LIBRARY,
APPLICATION TO THE DETECTION OF MYCOBACTERIA

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

RESPONSE TO SECOND RESTRICTION REQUIREMENT

In response to an Office Action dated March 13, 2003, and pursuant to 37 C.F.R.
§ 1.111, applicants submit the following amendments and remarks.

IN THE CLAIMS:

Please amend the claims as follows:

11. (Twice Amended) A purified polynucleotide, comprising an Open Reading
Frame contained within SEQ ID NO:1, wherein the polynucleotide is selected from:

(a) nucleotide 1,695,944 through nucleotide 1,696,441 of the *Mycobacterium*
tuberculosis chromosome;

(b) nucleotide 1,696,728 through nucleotide 1,697,420 of the *Mycobacterium*
tuberculosis chromosome;

(c) nucleotide 1,698,096 through nucleotide 1,699,892 of the *Mycobacterium*

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tuberculosis chromosome;

(d) nucleotide 1,700,210 through nucleotide 1,701,088 of the *Mycobacterium tuberculosis* chromosome;

(e) nucleotide 1,701,293 through nucleotide 1,702,588 of the *Mycobacterium tuberculosis* chromosome;

(f) nucleotide 1,703,072 through nucleotide 1,704,091 of the *Mycobacterium tuberculosis* chromosome;

(g) nucleotide 1,704,091 through nucleotide 1,705,056 of the *Mycobacterium tuberculosis* chromosome;

(h) nucleotide 1,705,056 through nucleotide 1,705,784 of the *Mycobacterium tuberculosis* chromosome;

(i) nucleotide 1,705,808 through nucleotide 1,706,593 of the *Mycobacterium tuberculosis* chromosome; or

(j) nucleotide 1,707,530 through nucleotide 1,708,648 of the *Mycobacterium tuberculosis* chromosome.

REMARKS

Applicants respectfully request reconsideration and further examination in view of the following remarks.

Claims 11, 13, and 51-52 are pending in this application. Claim 11 has been amended by deleting one of the recited sequences from the claim.

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The Office Action dated March 13, 2003, asserted that claims 11 and 52 are "generic to a plurality of patentably distinct species comprising 11 structurally and therefore patentably different nucleotide sequences." The Office required an election under 35 U.S.C. § 121 of a single disclosed species.

Applicants provisionally elect with traverse sequence (g) of claim 11 corresponding to a purified polynucleotide comprising an open reading frame contained in SEQ ID NO:1, where the polynucleotide is nucleotide 1,704,091 through nucleotide 1,705,056 of the *Mycobacterium tuberculosis* chromosome.

Applicants believe that sequence (g) of claim 11 should be examined with the other nine nucleotide sequences recited in claim 11. Section 803.04 of the M.P.E.P. states:

[T]o further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided *sua sponte* to partially waive the requirements of 37 C.F.R. 1.141 *et seq.* and permit a reasonable number of such nucleotide sequences to be claimed in a single application. *See Examination of Patent Applications Containing Nucleotide Sequences*, 1192 O.G. 68 (November 19, 1996).

It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction. In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined.

As amended, claim 11 recites ten nucleotide sequences, i.e., (a) through (j).

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Therefore, these ten sequences represent a reasonable number of sequences for examination purposes and should be examined together pursuant to the Office's restriction practice for applications claiming nucleic acid sequences, as set forth at section 803.04 of the M.P.E.P.

If there is any fee due in connection with the filing of this paper, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: April 14, 2003

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APPENDIX

IN THE CLAIMS:

Please amend the claims as follows:

11. (Twice Amended) A purified polynucleotide, comprising an Open Reading Frame contained within SEQ ID NO:1, wherein the polynucleotide is selected from:

(a) nucleotide 1,695,944 through nucleotide 1,696,441 of the *Mycobacterium tuberculosis* chromosome;

(b) nucleotide 1,696,728 through nucleotide 1,697,420 of the *Mycobacterium tuberculosis* chromosome;

(c) nucleotide 1,698,096 through nucleotide 1,699,892 of the *Mycobacterium tuberculosis* chromosome;

(d) nucleotide 1,700,210 through nucleotide 1,701,088 of the *Mycobacterium tuberculosis* chromosome;

(e) nucleotide 1,701,293 through nucleotide 1,702,588 of the *Mycobacterium tuberculosis* chromosome;

(f) nucleotide 1,703,072 through nucleotide 1,704,091 of the *Mycobacterium tuberculosis* chromosome;

(g) nucleotide 1,704,091 through nucleotide 1,705,056 of the *Mycobacterium tuberculosis* chromosome;

(h) nucleotide 1,705,056 through nucleotide 1,705,784 of the *Mycobacterium tuberculosis* chromosome;

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(i) nucleotide 1,705,808 through nucleotide 1,706,593 of the *Mycobacterium tuberculosis* chromosome; or

[(j) nucleotide 1,706,631 through nucleotide 1,707,524 of the *Mycobacterium tuberculosis* chromosome; or]

[(k)] nucleotide 1,707,530 through nucleotide 1,708,648 of the *Mycobacterium tuberculosis* chromosome.

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